REMARKS

This is the response to a first Office Action following entry of new claims concurrent with a Request for Continued Examination. Claims 33-60 have been examined. Claims 33-59 are rejected, and claim 60 is objected to solely as being dependent upon a rejected base claim, but which would be allowable to rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Amendments. Claim 60 is amended to include the limitations of claim 57, the sole independent claims from which it depends. Claim 60 is now an independent claim. It is asserted that claim 60, as amended, is properly allowable.

New Claim. New claim 61 is presented, based on claim 45, as to which the only objection was to use of the term "sufficient quantities" with respect to thrombopoietin and a thyroid regulatory agent. In new claim 61 ranges are specified for each of the steps of the method.

Claims Rejections. Claims 33-59 are rejected solely on the basis of 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed for the reasons set forth below.

Claims rejected using "sufficient quantities" as limitations. Claims 33-59 are rejected on the asserted grounds that the use of the words "sufficient quantities" is indefinite. It is asserted that "it is not clear what amount of thrombopoietin is used to induce endogenous production of platelet-derived growth factor in the mammal, or what amount of a thyroid regulatory agent is used to regulate cell division and oligodendroglia production."

When a term of degree is presented in a claim, the first issue is whether the specification provides some standard for measuring that degree. *See* MPEP § 2173.05(b); *Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371, 60 U.S.P.Q.2d 1272 (Fed Cir 2001). In *Exxon Research*, the claim at issued recited a time period as "for a period sufficient to increasing substantially the initial catalyst activity." The Federal Circuit Court of Appeals reversed the trial court's holding that the phrase was indefinite. With respect to the specific limitation "for a period sufficient" in the claim, the Federal Circuit Court of Appeals held that this was not indefinite. In so doing, the Federal Court noted that the

specification did not "quantify the 'period sufficient' limitation by reference to any specific period or range of periods...", but that the specification did provide some guidance as to at least the minimum time. 265 F.3d at 1378-79. Here, examination of the specification provides far more detail than appears to be the case in *Exxon Research*. With respect to actual quantities, ranges are disclosed for thrombopoietin (see, e.g., page 8, lines 1-4; page 9, lines 22-26) and for any of a wide variety of "regulatory agents", such as a thyroid hormone or substance stimulation thyroid production (see, e.g., page 9, lines 6-27).

More than merely giving ranges that provide a standard, the Applicant has further defined the functional role served by such agents. Thus, with respect to thrombopoietin and other enhancement agents, Applicant has stated that it is an agent that results in "the direct or indirect production of platelet-derived growth factor (PDGF)." (Page 6, line 16) See also page 8, lines 2-3, stating "[i]n the case of TPO, a therapeutically effective amount is administered, resulting in PDGF expression." Thus an objective measure is provided. With respect to "regulatory agents", it is specifically provided that such an agent "results in the direct or indirect alteration of cell division rates and induction of differentiation, specifically of oligodendrocyte cells." (Page 7, lines 1-3) A number of literature citations are provided which document this role, including assays and methods for determining the effect. See, e.g., the papers cited at page 7, lines 3-12.

As set forth in *Exxon Research*, all that is required is that "the claim limitation is expressed in terms that are reasonably precise in light of the subject matter." 265 F.3d at 1379. The claim limitation "sufficient quantities" is as precise as the subject allows. "Sufficient" thrombopoietin results in inducing endogenous product of PDGF. "Sufficient" thyroid regulatory agent results in regulation of cell division and oligodendroglia production. As stated in *Exxon Research*, "[p]rovided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation may be necessary to determine the scope of the claims does not render the claims indefinite." (Citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 U.S.P.Q. 303, 316 (Fed Cir 1983)). *See also* MPEP § 2173.05(c), analyzing the analogous phrase "effective amount." Applicant notes that, if it would advance prosecution

of the application, that the phrase "an effective amount" may be substituted for "sufficient quantities" in claims 33 and 45, the two terms being analogous and of similar scope.

Claims 33-44 indefinite for lacking essential step whereby the outcome can be determined. Applicant respectfully traverses this rejection, on the grounds that determining the outcome is not an essential step. As drafted, this is a claim for "inducing regeneration and repair of nerve axon myelin coatings." Whether or not an "outcome" step is conducted does not, in any way or to any extent, cause or affect the "regeneration and repair." At most, an outcome step would simply provide a validation of whether the method worked. It is not a step of the method. MPEP § 2172.01 provides guidance (albeit in the context of 35 U.S.C. § 112, first paragraph) on this issue; it states that "essential matter may include missing elements, steps ... necessary to practice the invention." There is no showing that an "outcome" step is necessary to practice the invention. Accordingly, there is no omitted step. Claim 33 has been amended to provide a "whereby" clause, to make clearer the scope of the claim. It is submitted that, on analysis of the claim as amended, a limitation drawn to an "outcome" is clearly neither proper nor required.

Claims 44 and 56 because of the term "at least ten days." As set forth above, it is respectfully submitted that the claim is not indefinite. As with "sufficient quantities", with respect to "regulatory agents", it is specifically provided that such an agent "results in the direct or indirect alteration of cell division rates and induction of differentiation, specifically of oligodendrocyte cells." (Page 7, lines 1-3) A number of literature citations are provided which document this role, including assays and methods for determining the effect. See, e.g., the papers cited at page 7, lines 3-12. Thus sufficient guidance is provided for determining the "maximal" days.

Formal Matters. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Account 13-4213. A duplicate of this paper is enclosed for accounting purposes. Filed herewith is a Petition for Extension of Time to September 20, 2002, with the appropriate fee.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached paper is captioned "**Version with Markings to Show Changes Made**."

Should the Examiner have any queries, suggestions or comments relating to a speedy disposition of the application, the Examiner is invited to call the undersigned. Allowance of the claims is respectfully requested.

Respectfully submitted,

PEACOCK, MYERS & ADAMS, P.C.

Date: September 20, 2002

By: _____

Stephen A. Slusher
Reg. No. 43,924
Direct Dial: (505) 998-6130

Attorney for Applicant
P.O. Box 26927
Albuquerque, New Mexico 87125-6927
Phone: (505) 998-1500
Fax: (505) 243-2542

Customer No. 005179

I:\AMDS\schwartz-236-OA2.doc

Version with Markings to Show Changes Made

33. (First Amended) A method of inducing regeneration and repair of nerve axon myelin coatings in a mammal with demyelination comprising:

systemically administering sufficient quantities of thrombopoietin to the mammal to induce endogenous production of platelet-derived growth factor in the mammal; and

systemically administering sufficient quantities of a thyroid regulatory agent to regulate cell division and oligodendroglia production,

whereby regeneration and repair of nerve axon myelin coatings in a mammal with demyelination is induced.

60. (First Amended) [The method of claim 57 wherein the quantity of thrombopoietin administered is] A method of inducing increased platelet production with secondary increased endogenous production of platelet-derived growth factor in a mammal, the platelet-derived growth factor serving as a therapeutic agent to stimulate regeneration or repair of nerve axon myelin coatings in a mammal with damaged neurons, the method comprising systemically administering from 1.0 to 100 μg/kg body weight per day of thrombopoietin to the mammal to increase platelet production, whereby endogenous production of platelet-derived growth factor is increased, thereby causing regeneration or repair of nerve axon myelin coatings.

Please add the following new claim:

--61. A method of inducing increased platelet production with secondary increased endogenous production of platelet-derived growth factor in a mammal, the platelet-derived growth factor serving as a therapeutic agent to stimulate regeneration or repair of nerve axon myelin coatings in a mammal with damaged neurons, comprising:

systemically administering from 1.0 to 100 μg/kg body weight per day of thrombopoietin to the mammal to induce endogenous production of platelet-derived growth factor in the mammal; and

systemically administering a thyroid regulatory agent to regulate cell division and oligodendroglia production, the thyroid regulatory agent selected from the group consisting of from about

0.10 to 0.125 mg per day of oral levothyroxine, from about 25 to 50 μg per day of oral liothyronine sodium, from about 32 to 160 μg per day of oral thyroglobulin, from about 15 to 120 mg per day of oral dessicated thyroid, and from about 50 to 200 μg per day of injected levothyroxine.--